510(K) SUMMARY

OPUS 10 DENTAL DIODE LASER SYSTEM

510(k) Number K 000990

Applicant's Name:

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or:

Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth St, NW
Washington, DC 20004
Tel: (202) 637-5794
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Date Prepared:

March 2000

Trade Name:

Opus 10 Dental Diode Laser System

Classification Name:

Laser Instrument, Surgical, powered

Classification:

FDA has classified a laser device as a class II device (product code GEX) and it is reviewed by the General & Plastic Surgery Panel.

Predicate Device:

OpusDent Ltd. believes that the Opus 10 Dental Diode Laser System is substantially equivalent to the Surgical Diode Laser 6020 (Sharplan Laser, Inc.) cleared under K953794 in terms of performance, technological characteristics and user interface.

In addition, the Opus 10 is substantially equivalent to the PulseMaster™ 1000 ST Dental Laser System (American Dental Technologies, Inc.) cleared under K972325, to the Aurora™ Diode Laser System (Premier Laser Systems, Inc.) cleared under K954316 to the same Aurora™ Diode Laser System cleared for additional indications under K972586 and K981379, and to the Dentek LD 15 Diode laser (Dentek Austria GMBH) cleared under K990608, in terms of intended use, indication for use, technological characteristics, user interface and performance.

Performance Standards:

The Opus 10 Diode Laser complies with:
U.S. Federal Performance Standards 21 CFR 1040.10 and 21 CFR 1040.11 for class IV Laser Products.

In addition, the device complies with the European Medical Directive 93/42/EEC concerning medical devices (Annex II) and with the voluntary standards, EN 60601-1, EN-60825-1, EN-601-2-22, CISPR 11, IEC 61000-4-2/3/4/5, EN55011 and IEC 801-2

Intended Use / Indication for Use:

The Opus 10 Dental Diode Laser System is intended for incision, excision, ablation, vaporization and/or coagulation (hemostasis) of oral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva).

The Indications for Use of the Opus 10 Dental Diode Laser System include:

Endodontology
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy

Periodontology
- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodental pocket)

Oral Soft Tissue Surgery
- Biopsy
- Operculectomy
- Gingivectomy
- Gingivoplasty
- Papillectomy
- Lesion (tumor) removal
- Leukoplakia
- Treatment of aphthous ulcers
- Fibroma removal
- Frenectomies and frenotomies
- Tissue retraction for impressions
- Incising and draining of abscesses
- Exposure of unerupted teeth

Device Description:

The Opus 10 Dental Diode Laser System may be used to perform several dental applications. Opus 10 uses advanced laser technology to incise, excise and ablate intraoral soft tissues. A Gallium Aluminum Arsenide (GaAlAs) solid state laser diode provides optical energy to oral soft tissues.

A fiber optic holed by an handpiece delivers the Opus 10 laser energy. A visible light emitted from the handpiece distal end pointouts the area of treatment. The optical power output and pulse may be adjusted to specific use requirements.

Substantial Equivalence:

There are no unique applications, indications, material or specifications presented herein. Evidence of equivalence has been demonstrated through:

- The Opus 10 intended use and indications for use were previously cleared by FDA for the predicate devices.
- The technical characteristics of the Opus 10 are similar to those of the Surgical Diode Laser 6020. Differences between the devices include distinct indications for use, reduced output power and some other minor technological differences.
- Laser output values of the Opus 10 are well within previous cleared values of the predicate Dental Diode Laser Systems as described.
- The predicate devices and other previous cleared lasers with similar energy output has a proven safety and effectiveness in the treatment of the claimed indications
- Safety and performance testing.

Therefore, we believe that the Opus 10 Dental Diode Laser System is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 2000

OpusDent, Ltd.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004

Re: K000990
Trade Name: Opus 10 Dental Diode Laser System
Regulatory Class: II
Product Code: GEX
Dated: March 26, 2000
Received: March 28, 2000

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K000990

Device Name: Opus 10 Dental Diode Laser System

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(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number K000990

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)

Donna R. Vochmer
(Division Sign-Off)
Division of General Restorative D

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